Key Words: antipsychotic agents, bipolar disorder, depression, double-blind method, mood disorders, psychiatric status rating scales, psychopathology, psychopharmacology, psychotic disorders, schizophrenia, tardive dyskinesia, valbenazine

Long-Term Safety and Tolerability of Valbenazine (NBI-98854) in Subjects with Tardive Dyskinesia and a Diagnosis of Schizophrenia or Mood Disorder

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ABSTRACT ~ **Background:** *The short-term safety profile of once-daily valbenazine (NBI-98854) has been evaluated in several double-blind, placebo-controlled (DBPC) trials in adults with tardive dyskinesia (TD) who had a diagnosis of schizophrenia/schizoaffective (SCHZ) disorder or mood disorder. Studies with longer treatment duration (up to 48 weeks) were conducted to evaluate the long-term safety of this novel drug in subjects with TD.* **Methods:** *The pooled long-term exposure (LTE) population included valbenazine-treated subjects from 3 studies: KINECT (NCT01688037: 6-week DBPC, 6-week open-label); KINECT 3 (NCT02274558: 6-week DBPC, 42-week blinded extension, 4-week drug-free follow-up); KINECT 4 (NCT02405091: 48-week open-label, 4-week drug-free follow-up). Safety assessments included adverse events (AEs), laboratory tests, vital signs, electrocardiograms (ECGs), and extrapyramidal symptom (EPS) scales. Psychiatric stability was monitored using the Positive and Negative Syndrome Scale (PANSS) and Calgary Depression Scale for Schizophrenia (CDSS) (SCHZ subgroup), as well as the Montgomery-Åsberg Depression Rating Scale (MADRS) and Young Mania Rating Scale (YMRS) (mood subgroup). All data were analyzed descriptively.* **Results:** *The LTE population included 430 subjects (KINECT, n = 46; KINECT 3, n = 220; KINECT 4, n = 164), 71.7% with SCHZ and 28.3% with a mood disorder; 85.5% were taking an antipsychotic (atypical only, 69.8%; typical only or typical + atypical, 15.7%). In the LTE population, treatment-emergent AEs (TEAEs) and discontinuations due to AEs were reported in 66.5% and 14.7% of subjects, respectively. The TEAE incidence was lower in the SCHZ subgroup (64.4%) than in the mood subgroup (71.9%). The 3 most*

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